IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDTECH PRODUCTS INC., 90 North Broadway Irvington, New York 10533 Plaintiff, v. POWER PRODUCTS, INC. d/b/a SPLINTEK, 3325 Wyoming Street Kansas City, Missouri 64111 Defendant.	Civil Action No. 07 CV 3305 (SCR)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF MEDTECH PRODUCTS INC.'S MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

Plaintiff MEDTECH PRODUCTS INC. ("Medtech") respectfully submits this Memorandum of Law in Support of its Motion for Preliminary Injunction, pursuant to FED. R. CIV. P. 65(a), seeking a preliminary injunction enjoining the Defendant, POWER PRODUCTS, INC. d/b/a SPLINTEK ("Power Products" or "SPLINTEK") from continuing to wrongfully infringe upon, profit from, and/or damage Medtech's reputation, trademarks and copyrights.

This case involves dental protectors that are designed to protect the teeth and jaw from the detrimental effects of teeth grinding (known as bruxism). Since 1997, Medtech has pioneered the over-the-counter ("OTC") sale of dental protectors. Medtech's product is sold under the trademarks THE DOCTOR'S® NIGHTGUARD™ (hereinafter "NIGHTGUARD"), and nationally generates more than ten million dollars in annual sales for Medtech.

Power Products has launched a campaign to lure consumers into purchasing its dental protector product by marketing it using the name "NIGHT GUARD." By incorporating Medtech's NIGHTGUARD mark, Power Products designed its campaign to cause consumer confusion. Power Products is also unlawfully marketing and selling its dental protector for OTC use. Power Products has obtained approval from the U.S. Food and Drug Administration ("FDA") to market its device in the United States only by prescription. By marketing and selling its dental protector OTC, Power Products is directly violating the terms of its FDA approval.

Power Products' recent activities pose a threat of substantial urgency. Within the past few weeks, Power Products has expanded the scope of its illegal OTC sales of dental protectors. At the time this lawsuit was filed, the Power Products website at www.sleepright.com only listed a handful of retail locations where its dental protector was available. Declaration of Manning ("Manning Decl.") ¶ 2 & Ex. 1. However, after this lawsuit was filed, Power Products began selling its product at Target retail stores, including stores based in New York. *Id.* ¶ 3 & Ex. 2.

Target is a national retail chain that sells Medtech's NIGHTGUARD brand dental protectors. Declaration of Schrank ("Schrank Decl.") ¶ 7. Medtech has also received information from independent commercial monitoring services that Power Products began to sell its products in the Michigan based Meijer food chain beginning in the last week of March 2007. *Id.* ¶ 16.

Power Products is wrongfully benefiting from Medtech's hard-won commercial success, advertising campaigns, and well-earned consumer trust in THE DOCTOR'S® NIGHTGUARD. Medtech bases this motion for preliminary injunctive relief upon the following three claims: (a) unfair competition under the Lanham Act, 15 U.S.C. § 1125(a) (hereinafter "Section 43(a)"); (b) copyright infringement under 17 U.S.C. § 501; and (c) unfair competition under N.Y. Gen. Bus. Law § 349 (hereinafter "Section 349"). Power Products' expanded market presence and increased direct competition with Medtech's NIGHTGUARD dental protector pose an immediate and urgent threat to Medtech. The damage being caused is inestimable and irreparable in a market where consumer confidence, brand recognition and reputation are critical to success. Immediate injunctive relief is necessary to protect Medtech's reputation, goodwill, and business from Power Products' continued infringing actions.

II. FACTS

A. MEDTECH'S INVESTMENT IN THE NIGHTGUARD PRODUCT AND MARK.

1. MEDTECH HAS CONSISTENTLY FEATURED THE NIGHTGUARD MARK IN ITS PACKAGING AND ADVERTISING.

Medtech markets, distributes, and sells a dental protector designed to protect the teeth and jaw from the detrimental effects of bruxism under the trademarks THE DOCTOR'S® NIGHTGUARD. *See* Schrank Decl. ¶ 2. Medtech's predecessor-in-interest, Dental Concepts LLC, began using the NIGHTGUARD mark for its dental protectors on or about January 1997. (Dental Concepts and Medtech are collectively referred to as "Medtech.") *Id.* ¶ 3. From January

1997, and for several years thereafter, the NIGHTGUARD product was the only significant dental protector on the OTC market and has generated substantial consumer recognition. *Id.*

Medtech's packaging and advertising always featured the NIGHTGUARD mark. From January 1997 through the present, Medtech's THE DOCTOR'S® NIGHTGUARD™ packaging has consistently and prominently featured the NIGHTGUARD mark on the front of the packaging. Medtech's product packaging (hereinafter referred to as Medtech's NIGHTGUARD "Trade Dress") is pictured in Part A of the Appendix hereto. *See also id.* ¶ 4 & Exs. A-B. Moreover, Medtech sells the NIGHTGUARD dental protector with an insert captioned "At-Home Fitting Instructions" that describes the dental protector product and how the customer should use the product. *Id.* ¶ 6 & Ex. C. The "At-Home Fitting Instructions" have been developed specifically for use with the NIGHTGUARD dental protector since October 2006. *Id.*

2. MEDTECH WAS THE FIRST COMPANY TO OBTAIN FDA APPROVAL FOR AN OTC DENTAL PROTECTOR.

On March 3, 2006, Medtech became the first company to obtain formal FDA approval for an OTC dental protective device for night time tooth grinding or bruxism. Declaration of Boyko ("Boyko Decl.") ¶ 2 & Ex. 1. Prior sales of the NIGHTGUARD dental protective device were made OTC with the knowledge of the FDA but without formal approval. *Id.* ¶ 3. Subsequent to the FDA approval in the Fall of 2006, Medtech changed its Trade Dress and revised its labeling to conform to the new FDA approval. Beginning in January 2007, Medtech's television advertising featured the purple, red, and white Trade Dress and new labeling. Schrank Decl. ¶ 5.

3. THE SUCCESS OF THE NIGHTGUARD DENTAL PROTECTOR.

Medtech has spent thousands of hours and millions of dollars in marketing and promoting dental protector products under the NIGHTGUARD mark through extensive radio and television advertising campaigns. *Id.* ¶ 8. In the past three years alone, Medtech has spent more than

$8,000,000 in advertising and promotion to build the NIGHTGUARD brand name. *Id.* Since use of the NIGHTGUARD mark began, Medtech has used the mark to market its dental protector through advertisements, on nationally syndicated radio networks and shows, and on cable television. *Id.* Exemplars of the television advertisements, which consistently display or include the NIGHTGUARD mark, are attached to the Schrank Decl. as Exhibits D and E.

Medtech's marketing efforts have born substantial fruit and strengthened brand recognition. As a result of Medtech's recent cable advertising campaign, sales increased dramatically from an average of 53,000 units per month to an average of 89,000 units per month (a 68% increase in sales). *Id.* ¶ 10 & Ex. F. Over the past six years, Medtech has sold more than $43,000,000 of its NIGHTGUARD dental protector products. *Id.* ¶ 9. The NIGHTGUARD mark has become firmly associated in the minds of the consuming public with the high-quality dental protector product marketed and sold by Medtech. A recent survey of consumers revealed that 67% of the consumers that had heard of the NIGHTGUARD mark associated it with a dental protector brand name. Declaration of Eugene Ericksen ("Ericksen Decl.") ¶¶ 2-3 & Ex. AA.

By virtue of its long-standing success, the NIGHTGUARD trademark, and the high-quality characteristics of Medtech's THE DOCTOR'S® NIGHTGUARD product, have become associated exclusively with Medtech, and are of great value to Medtech. As a result, Medtech has made efforts to protect its intellectual property in several different ways:

[1] ***Patent***. The NIGHTGUARD dental protector is covered by valid U.S. Patent No. 6,830,051, issued by the U.S. Patent and Trademark Office on December 14, 2004. Schrank Decl. ¶ 19 & Ex. J.

[2] ***Copyright Registration***. Medtech has registered its copyrights in the "At-Home Fitting Instructions" and current packaging of the NIGHTGUARD dental protector with the U.S. Register of Copyrights (U.S. Reg. No. TX 6-536-309, issued April 23, 2007) (the "Copyright Registration"). *Id.* ¶ 20 & Ex. K.

[3] ***Trademark Application***. Medtech owns a pending federal trademark application for its NIGHTGUARD mark (NIGHTGUARD, Ser. No. 77/056,556, United States Patent and Trademark Office). *Id.* ¶ 21.

B. POWER PRODUCTS' INFRINGING ACTIVITIES.

Power Products is currently marketing and selling an OTC dental protector for nighttime tooth grinding or bruxism using the mark "NIGHT GUARD." *Id.* ¶ 11. In marketing and selling its OTC dental protector, Power Products is improperly utilizing Medtech's NIGHTGUARD mark and substantial portions of Medtech's copyrighted material. The Power Products' dental protector, in addition to using Medtech's intellectual property, is being sold OTC illegally and without the required regulatory approval. Despite a Warning Letter from the FDA, Boyko Decl. ¶ 8 & Ex. 5, Power Products continues to illegally market and sell its dental protector OTC. Power Products has even expanded its market presence since this lawsuit was filed to include the national retailer Target. Manning Decl. ¶¶ 2-3.

1. POWER PRODUCTS HAS COPIED MEDTECH'S BRAND NAME AND COPYRIGHTED MATERIAL.

In marketing its product, Power Products has copied Medtech's NIGHTGUARD trademark. The Power Products package prominently displays the "NIGHTGUARD" mark on the front cover, as pictured in Part B of the Appendix. *See also* Schrank Decl. ¶ 11 & Ex. G. While the package depicts the product as "ADJUSTABLE NIGHT GUARD," Power Products often refers to the product as its "Nightguard"—one word, capitalized, with no modifier. For instance, on the Power Products web site (www.sleepright.com), Power Products has set up a "Customer Posts" segment, which redirects the Internet user to a "SPLINTEK® Community Forum." Manning Decl. ¶ 4 & Exs. 3-4. Included in the forum are posts from Power Products' "Community Moderators." *Id.* These Power Products employees and representatives appear charged with answering questions about the Power Products' dental protector and use the NIGHTGUARD mark in a non-generic way when answering questions and discussing the Power Products' dental protector. *Id.* at ¶ 4 & Ex. 3. Examples are found in Part C of the Appendix.

Similarly, when describing the Power Products' dental guard or dental protector, the Frequently Asked Questions section on Power Products' website consistently refers to the Power Products' dental protector as "The SleepRight Night Guard," while describing the product type as, alternatively, a dental guard, intra-oral appliance, or splint:

- "First, there are many different ***designs for dental guards*** available from the dental professional. Our ***SleepRight Night Guard*** (SRNG) is considered a posterior type splint / appliance, similar to many other posterior splints made in the dental office, without the much higher cost of course. . . ."
- "***The SleepRight Night Guard*** (SRNG) uses natural tissue retention between your lips, cheeks and tongue to be held in place. . . . it is common knowledge in orthodontic practices that many orthodontic patients find their removable ***intra-oral appliances*** on the bed when they awaken, especially during the first few nights . . . ."
- "***The SleepRight Night Guard*** (SRNG) was designed by a specialist in dentistry to protect teeth and jaw joints from the neuromuscular disorder commonly referred to as clenching and grinding (C & G) teeth. . . . ***Splints are appliances routinely used in the dental office*** as the first line of defense against chronic C & G's . . . ." Manning Decl. ¶ 5 & Ex. 5 (emphasis added).

Power Products also has copied Medtech's copyrighted material. On Power Products' web site, warnings and disclaimers are copied extensively from the warnings included in the NIGHTGUARD "At-Home Fitting Instructions." *Compare* Schrank Decl. ¶ 6, Ex. C (Medtech's "At-Home Fitting Instructions" at pg. 3, "Warnings") *with* Manning Decl. ¶ 6, Ex. 6 (Power Products' Warnings, listed after "Caution"). Notwithstanding the significant differences in the two products, the Power Products' warnings are copied verbatim from Medtech's "At-Home Fitting Instructions." A comparison of the warnings is included in Part D of the Appendix.

2. POWER PRODUCTS RECENT ADOPTION OF THE NIGHTGUARD MARK.

Power Products' use of the Night Guard mark appears to be a relatively recent marketing decision that coincides with the success of the NIGHTGUARD devices. For instance, on September 4, 1998, after Medtech had been using the NIGHTGUARD mark for over a year-and-a-half, Power Products applied for its SPLINTEK trademark. Manning Decl. ¶ 7, Ex. 7. In its

application, Power Products described the goods and services of SPLINTEK as "***dental mouth guards*** for medical purposes" (emphasis added). *Id.* Tellingly, Power Products did not use "Night Guard" at that time.

Five years later, Power Products still was not using "Night Guard." On or around July 16, 2003, at the time Power Products received the 510(k) approval for their prescription-only device, the "common name" identified for their product was an "*Oral Occlusal Appliance or Splint.*" Boyko Decl. ¶ 4, Ex. 2. At this time, Medtech had been using the THE DOCTOR'S® NIGHTGUARD brand for over six-and-a-half years.

Since the FDA approval of THE DOCTOR'S® NIGHTGUARD for OTC use, Power Products began frequently to use the NIGHTGUARD mark on its packaging and advertising. Power Products' intent behind this use is shown by the fact that even in its own "Care and Fitting Instructions," which the consumer receives with its purchase, Power Products simply refers to the product as the "SleepRight," without using the "NIGHTGUARD" mark:

- "Warm water will activate the thermal properties of the SleepRight strap."
- "Your SleepRight has been pre-adjusted . . ."
- "The thermal SleepRight strap . . ."
- "Your SleepRight has 4 notches . . ."
- "If yellowing occurs, consider a new SleepRight."
- "The SleepRight's articulating bitepads . . . ."

Schrank Decl. ¶ 11, Ex. H.

3. THE POWER PRODUCTS DENTAL PROTECTOR IS OF INFERIOR QUALITY.

The Power Products dental protector is an adjustable, pre-formed oral appliance that includes two bite pads. Boyko Decl. ¶ 5. Unlike THE DOCTOR'S® NIGHTGUARD product,

the Power Products' dental protector is not a full occlusion mouthpiece.[1] It does not provide complete protection against bruxism, and its bulky bite pads create discomfort during use. Moreover, devices which are not fully occlusive are deemed by FDA to require the active oversight and intervention of a dentist due to the risk of causing damage to the teeth by "super eruption." *Id.* ¶¶ 5-9.

Even a cursory review of the customer postings on the Power Products' Community Forum reveals the potential for extreme dissatisfaction with Power Products' dental protector, with customers stating that they "can't believe that they can sell the Sleepright!" because it is "[v]ery uncomfortable." Manning Decl. ¶ 4 & Ex. 4. Other customers note that they "are completely unsatisfied with this product. It caused me more pain than I was experiencing before purchasing the product." Still others found that the Power Products' product was a "rip off" and a "gimmick." *Id.* Some examples of community postings are found in the Part E Appendix.

Remarkably, even though the Power Products product is of inferior quality, it is more expensive than Medtech's product. Power Products sells its dental protectors at retail price points between $34.95 for the "Low-Profile" and "Select" products, to $99.95 for the "Advance" dental protector. Schrank Decl. ¶ 17. These prices greatly exceed Medtech's average retail price of $24.99. *Id.* ¶ 18. Power Products customers are unlikely to return to the OTC dental protector market after such an expensive and frustrating product experience, and, most importantly, now are likely to associate the name "NIGHTGUARD" with their unsatisfactory experience.

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[1] "Occlusion" in this context means "[a]lignment of the mandibular and maxillary teeth when ***the jaw is closed*** or ***in functional contact***." *Taber's Cyclopedic Med. Dictionary*, 1938 (19th ed., F.A. Davis Co.) (2001) (emphasis added). The Medtech NIGHTGUARD dental protector is designed to fit over the entirety of the top teeth, bringing the top teeth fully in contact with the bottom teeth, with the dental guard in between ("full-occlusion"). The Power Products' dental protector has two separate bite pads, designed just for the rear teeth, leaving the top teeth out of contact with the bottom teeth (not "full-occlusion").

4. POWER PRODUCTS IS SELLING ITS PRODUCT ILLEGALLY.

In addition to the violations described above, Power Products is selling its dental protector in violation of FDA regulations. Power Products received a Section 510(k) premarket authorization from the FDA for dental protectors for **prescription use only**, and for patients 18 years of age or older. *See* Boyko Decl. ¶ 4 & Ex. 2. The Section 510(k) premarket authorization for the Power Products' dental protector was marked for "**Prescription Use (Per 21 C.F.R. 801.109)**" under the FDA approval letter. *Id.* (Ex. 2 at Attachment 3).[2] Power Products' OTC sales ignore this limited authorization. As a matter of course, a product which is sold in violation of a "prescription only" restriction has inadequate directions for use by a layman, rendering the product "misbranded." Specifically, the Power Products devices carry no warning or instruction concerning the risk of "super eruption," which is a principal reason why partial occlusion devices are restricted to prescription use. Indeed, most laymen could not recognize or define "super eruption." 21 U.S.C. § 352(o) ("A drug or device shall be deemed to be misbranded—. . . if a notice or other information respecting it was not provided as required by . . . section 360(k) of this title . . ."). *See also* Boyko Decl. ¶ 8 & Ex. 5 (Warning Letter from FDA stating that the Power Products device is being illegally marketed and is "misbranded").

As the Power Products product is not a full-occlusion mouthpiece, selling it OTC would be contrary to both the FDA's determination that non-fully occlusive nighttime protective devices involve an unacceptable risk of super eruption (if not prescribed and overseen by a

[2] Under Section 510(k), every person "who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall" register that device with the FDA. 21 U.S.C. § 360(k). Under 21 C.F.R. 801.109, as referenced in the Power Products' Section 510(k) authorization, the product can "be sold only to or ***on the prescription or other order of such practitioner*** [licensed by law to direct the use of such device] for use in the course of his professional practice." 21 C.F.R. 801.109(a)(2).

dentist) and the FDA's Dental Advisory Panel's independent recommendation that only full occlusion mouthpieces should be permitted to be sold OTC. Boyko Decl. ¶¶ 5-6 & Ex. 3. Nevertheless, Power Products' dental protector product is being illegally marketed OTC. Medtech, acting through counsel, alerted the FDA to Power Products' conduct on October 20 and November 22, 2006. *Id.* ¶ 7 & Exs. 3-4. The FDA determined that Power Products' OTC sales were illegal and issued a "WARNING LETTER," dated January 16, 2007, that stated:

> The Food and Drug Administration (FDA) has learned that your firm is marketing the Sleep Right® Adjustable Night Guard in the United States (U.S.) for over the counter use to protect teeth from clenching and grinding, and for use by children 12 – 18 years old, without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).
>
> * * *
>
> A review of our records reveals that you have obtained marketing clearance (K022809) for the Right® [sic.] Adjustable Night Guard for prescription use only, and for patients 18 years of age or older. However, you have not obtained marketing approval or clearance before you began offering your product for over the counter use and for use by children 12 – 18 years old, which is a violation of the law. (Boyko Decl. ¶ 8 & Ex. 5.)

In referencing marketing to children 12 to 18 years old, the FDA was discussing the "At-Home Fitting Instructions" which are included with the Power Products' product. Schrank Decl. ¶ 11 & Ex. H. The warnings on the product only restrict for "children under 12 years of age":

> For all TMJ concerns, please consult your health care provider who may prescribe a SleepRight Rx. Do not use for more than 12 hours in a 24 hour period. Recommended for day time or night time use, not both. Not for children under **12** years of age. If you experience jaw pain, clicking, jaw noises, tooth movement, or other symptoms, see your health care provider. Discontinue use and replace if breakage occurs. (*Id.*)

FDA has reaffirmed its position on the inappropriateness of non-fully occlusive dental protective devices for OTC use as recently as March 8, 2007 in a meeting with concerned representatives of Medtech. Boyko Decl. ¶ 9. Despite the WARNING LETTER from the FDA, Power Products continues to offer for sale OTC its dental protector product, both in stores and

over the Internet. *See* Manning Decl. ¶¶ 2-3 & Exs. 1-2. In fact, Power Products has very recently expanded its sales in the OTC retail market with the addition of Target to the list of retail stores where its illegal product is sold. *Id.* Given Power Products' infringing use of the NIGHTGUARD brand name, Medtech will be unfairly associated with Power Products' illegal marketing and sales of OTC dental protectors.

C. MEDTECH'S INJURIES.

Medtech has incurred substantial injuries as a result of Power Products' multiple infringements. Customers are confused by Power Products' use of the NIGHTGUARD mark and copying of Medtech's instructions and warning. This is demonstrated by Medtech's lost sales and revenues since the Power Products product entered the OTC market, and its loss of market share. Schrank Decl. ¶¶ 14-15 & Ex. I. Power Products' usurpation of Medtech's efforts to promote the NIGHTGUARD brand are clearly shown by the results of Medtech's advertising campaign on cable television: in most retail stores, sales of Medtech NIGHTGUARD dental protector increased substantially, while in the one chain of retail stores where Power Products had entered into direct competition with Medtech, Longs Drugs, Medtech's sales did not increase; rather, the increase in sales in the market went to the infringing Power Products' dental protector. *Id.*; Manning Decl. ¶ 8 & Ex. 8 (Power Products' store locations in California).

Not only will Medtech lose sales and revenues as confused customers buy Power Products' product when they intended to buy Medtech's product, but Power Products' conduct will continue to damage Medtech's ability to maintain its hard-won brand recognition and reputation in the OTC dental protector category. Negative customer comments about the Power Products' dental protector demonstrate the adverse customer reaction, and demonstrate that the reputation of the Medtech NIGHTGUARD dental protector likely will be adversely affected as well. *See* Manning Decl. ¶ 4, Ex. 4.

Further damage and irreparable injury will result if Power Products is allowed to continue to violate Medtech's rights by marketing an illegal and inferior product utilizing Medtech's NIGHTGUARD mark, especially when that product is priced much higher than Medtech's product. *See* Schrank Decl. ¶¶ 16-18. Consumers who purchase the Power Products dental protector will likely feel deceived and cheated given the poor quality of the product, and will be unlikely to purchase other dental protectors as a result.

III. ARGUMENT

A. THE PRELIMINARY INJUNCTION STANDARD.

Medtech seeks a preliminary injunction to enjoin further infringing conduct by Power Products of Medtech's intellectual property based on unfair competition under the Lanham Act, copyright infringement, and deceptive acts and practices. In the Second Circuit, a preliminary injunction is appropriate if Medtech shows: (1) either a likelihood of success on the merits, or that there are sufficiently serious questions going to the merits and the balance of hardships tips decidedly its way; and (2) that it will suffer possible irreparable harm in the absence of the requested relief. *Sunward Electronics, Inc. v. McDonald et al.*, 362 F.3d 17 (2d Cir. 2004); *Fisher-Price, Inc. v. Well-Made Toy Mfg. Corp.*, 25 F.3d 119, 122 (2d Cir. 1994) (copyright).

B. POWER PRODUCTS SHOULD BE ENJOINED FROM USING THE "NIGHTGUARD" MARK.

1. FIRST FACTOR: MEDTECH HAS SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS OF ITS LANHAM ACT CLAIM.

Power Products has attempted to pass off its dental protector product as if it came from Medtech, or otherwise is a NIGHTGUARD dental protector. Power Products' use of the NIGHTGUARD mark constitutes trademark infringement in violation of Section 43(a) of the Lanham Act. 15 U.S.C. § 1125(a) ("[a]ny person…uses in commerce any word, term, name, symbol, or device…likely to cause confusion or to cause mistake, or to deceive as to the

affiliation, connection, or association of such person with another person . . ."). Medtech is entitled to relief if it establishes that: 1) the mark is protectable, and 2) there is a likelihood of confusion. *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 454 F.3d 108, 115 (2d Cir. 2006).

a. MEDTECH'S THE DOCTOR'S® NIGHTGUARD IS A PROTECTABLE MARK.

Medtech has spent over ten years and an extraordinary amount of effort establishing THE DOCTOR'S® NIGHTGUARD mark. The Lanham Act defines a trademark as "any word, name, symbol, or device, or any combination thereof" which is used or intended to be used by a person "in commerce . . . to identify and distinguish his or her goods . . . from those manufactured or sold by others and to indicate the source of the goods, even if that source is unknown." 15 U.S.C. § 1127. To establish protectability under Section 43(a), "a mark must be sufficiently 'distinctive' to distinguish the registrant's goods from those of others. A plaintiff can establish a mark as distinctive by showing that the mark is 'inherently distinctive,' *i.e.,* intrinsically capable of identifying its source, or by demonstrating that the mark has acquired 'secondary meaning.'" *Louis Vuitton Malletier,* 454 F.3d at 116 (*quoting Star Indus. v. Bacardi & Co.*, 412 F.3d 373, 381 (2d Cir. 2005)).

Medtech's NIGHTGUARD mark is protectable because it is suggestive. "A suggestive mark is one that 'suggests the product, though it may take imagination to grasp the nature of the product.'" *Estee Lauder Inc. v. The Gap, Inc.*, 108 F.3d 1503, 1509 (2d Cir. 1997) (*quoting Gruner+Jahr USA Publishing v. Meredith Corp.*, 991 F.2d 1072, 1076 (2d Cir. 1993)). The NIGHTGUARD mark does not simply describe the features of a nighttime dental protector. *See Bristol-Myers Squibb Co. v. McNeil – P.P.C., Inc.*, 973 F.2d 1033, 1040 (2d Cir. 1992) (stating that a descriptive mark "forthwith conveys an immediate idea of the ingredients, qualities or characteristics of the goods" (internal citations and quotations omitted)). Rather, the

NIGHTGUARD mark suggests that the product guards something at night, but requires "imagination, thought and perception to reach a conclusion as to the nature of the goods." *See id.* (internal citations and quotations omitted). Without imagination, thought and perception, the consumer could not conclude that the NIGHTGUARD brand product is a dental protector that ***guards*** teeth from the damaging effects of bruxism at ***night***.

A suggestive mark is protected without a showing of secondary meaning. *Estee Lauder Inc.*, 108 F.3d at 1509. Even if the NIGHTGUARD mark were found to be descriptive, rather than suggestive, it has acquired secondary meaning and is protectable. *Id.* ("Secondary meaning attaches to a mark when 'the consuming public primarily associates the term with a particular source.'" (internal quotations omitted)). As the leader of the OTC dental protector industry, Medtech's dental protector was the only OTC dental protector available for a number of years. For the entirety of the time, Medtech's product was marketed using the NIGHTGUARD mark. The NIGHTGUARD mark has been extensively marketed by Medtech through a national advertising campaign on syndicated radio networks and cable television. Medtech has been using the NIGHTGUARD mark continuously for over ten years in association with its dental protector. This extrinsic market evidence supports the claim of secondary meaning.

Moreover, the Court simply just has to the listen to the consumer reaction to know that the NIGHTGUARD mark has acquired secondary meaning. A recent survey revealed that 67% of consumers who recognized the NIGHTGUARD mark recognized it as a dental protector product trademark. Ericksen Decl. ¶¶ 2-3 & Ex. AA. The consumer survey was conducted by Eugene Ericksen, a Professor of Sociology and Statistics at Temple University and a robustly qualified expert witness. Mr. Ericksen's study concluded:

> The survey results indicate that 66 percent of respondents had heard of NIGHTGUARD. Of respondents who had heard of NIGHTGUARD, about 67

percent identified the term as a brand name. Based on these results, it is my opinion that NIGHTGUARD is a phrase associated with a particular brand and thus is not a generic term.

Id. The consuming public associates the NIGHTGUARD brand with Medtech's product.

b. POWER PRODUCTS' UNAUTHORIZED USE OF THE NIGHTGUARD MARK CAUSES A CLEAR LIKELIHOOD OF CONFUSION.

In evaluating the likelihood of confusion, courts consider the factors set forth in *Polaroid Corp. v. Polaroid Elecs. Corp.*, 287 F.2d 492, 495 (2d Cir. 1961): (i) strength of the mark; (ii) degree of similarity between the two marks; (iii) proximity of the products; (iv) actual confusion; (v) the likelihood of the plaintiff bridging the gap; (vi) infringer's good faith in adopting its mark; (vii) quality of infringer's product; and (viii) sophistication of the buyers. *Louis Vuitton Malletier,* 454 F.3d at 117; *Federal Express Corp. v. Federal Espresso, Inc.*, 201 F.3d 168, 171-72, 174 (2d Cir. 2000). The test is "non-exclusive" and the similarity of the marks is "a key factor in determining the likelihood of confusion." *Louis Vuitton Malletier,* 454 F.3d at 117.

In this case, an analysis of the *Polaroid* factors compels a finding of a likelihood of confusion. First, the NIGHTGUARD mark is strong. "[T]he strength of a mark depends ultimately on its distinctiveness, or its 'origin-indicating' quality, in the eyes of the purchasing public." *Guinness United Distillers & Vintners v. Anheuser-Busch, Inc.*, No. 02 CIV. 0861, 2002 WL 1543817, *3 (S.D.N.Y. July 12, 2002) (internal citations omitted).[3] Medtech's NIGHTGUARD mark has been in continuous use for over 10 years in conjunction with the sale of OTC dental protectors and has been the widely-recognized source of OTC dental protectors for several years. Medtech's NIGHTGUARD brand dental protectors have seen commercial success and increasing sales. And a recent survey of consumers revealed that 67% who had

[3] Copies of the unpublished cases are attached hereto as Exhibit 1.

heard of NIGHTGUARD recognized NIGHTGUARD as a dental protector product trademark. Ericksen Decl. ¶¶ 2-3 & Ex. AA.

Second, the mark used by Power Products in conjunction with its goods is substantially identical to the Medtech NIGHTGUARD mark. Both products prominently display the NIGHTGUARD mark on the front of the packaging. It is also clear that Power Products has demonstrated its intent to consistently refer to its product as a "Nightguard," as evidenced by the representations of its employees and agents on the Power Products web page, and other materials available on its web site.

Third, the Power Products dental protector and the NIGHTGUARD dental protector are similar products that are competing in the identical market. Both the SPLINTEK® dental protector and THE DOCTOR'S® NIGHTGUARD dental protector are designed—with different degrees of effectiveness—to protect the consumer from nighttime teeth grinding. Both are oral appliances. Both are being marketed to the same consumer, often in the same store.

Fourth, due to the recent nature of Power Products' infringing activity, Medtech has only begun investigating whether actual confusion has occurred. However, after Medtech's television campaign, sales of Power Products' dental protector through Longs Drugs outlets increased markedly. Schrank Aff. ¶¶ 14-15 & Ex. I. In most retail stores, after the television campaign, sales of Medtech NIGHTGUARD dental protector increased substantially. *Id.* The increase in sales in Longs Drugs of the Power Products' dental protector, at a time of increased advertising by Medtech, is indicative of actual confusion in the marketplace.

Fifth, there is no "gap" to bridge. This relates to Medtech's interest in "being able to enter a related field" and is not implicated here. *See Phillip Morris USA, Inc. v. Cowboy Cigarette Inc.*, No. 03 Civ. 2292 (JSR), 2003 WL 22852243, *3 (S.D.N.Y. Dec. 2, 2003).

Sixth, Power Products is not an innocent infringer. Power Products clearly knew about Medtech's product, as evidenced by its copying of Medtech's warnings and its adoption of Medtech's NIGHTGUARD trademark after it reached a high-level of commercial success. Further, Power Products had opportunities to call its product "NIGHTGUARD" in the past, and chose to use the descriptors "splint" or "appliance" or "dental mouth guard" instead. Bad faith can be inferred because of the strong similarities between Power Products use of the NIGHTGUARD mark, coupled with its earlier—and different—identifiers:

> In determining a defendant's intent, 'actual or constructive knowledge' of the prior user's mark or dress may indicate bad faith. Where such prior knowledge is accompanied by similarities so strong that it seems plain that deliberate copying has occurred, we have upheld findings of bad faith.

Paddington Corp. v. Attiki Importers & Distribs., Inc., 996 F.2d 577, 587 (2d Cir. 1993). *See also Phillip Morris USA, Inc.*, 2003 WL 22852243, *4 ("copy-cat" quality was strong evidence of bad faith).

Seventh, Medtech does not participate in the manufacture, distribution, inspection, or in any other way ensure the quality of, Power Products' product, and there is at least some likelihood that some consumers will be disappointed. This is buttressed by the fact that some online users have already expressed dissatisfaction with the product. *See* Appendix, Part E. Goods "that do not meet the trademark owner's quality control standards will not be considered genuine goods, and their sale will constitute trademark infringement." *Polymer Technology Corp. v. Mimran*, 37 F.3d 74, 78 (2d Cir. 1994) (internal citations omitted). "This is so because 'trademark law... serves to guarantee the quality of the trademarked product', and the sale of inferior goods with a true mark will clearly undermine the value of the trademarked brand as a guarantor of quality." *Id.* at 78 (citation omitted).

Finally, the eighth Polaroid factor looks to the sophistication of the buyers to determine a likelihood of confusion. The public is extremely unsophisticated as to the difference in corporate identity between Medtech and Power Products, and the likelihood of confusion is almost certain due to the identical marks and similar goods and services. Even the retailers, who buy the goods and services directly from Power Products, are not universally so sophisticated as to immediately perceive the difference between Medtech's and Power Products' use of the NIGHTGUARD mark. Thus, this factor also weighs in favor of a finding of likelihood of confusion.

Accordingly, the *Polaroid* factors weigh in favor of finding a likelihood of confusion. Medtech has shown a clear likelihood of success on the merits of its claim for trademark infringement, including a clear likelihood of confusion from Power Products' use of the NIGHTGUARD mark in the United States, and thus a presumption of irreparable harm. In addition to being irreparable, the harm accruing to Medtech from Power Products' wrongful activity is both serious and unquantifiable. Power Products must be enjoined from using the NIGHTGUARD mark to market its competing dental protectors.[4]

2. SECOND FACTOR: IRREPARABLE HARM TO MEDTECH IS UNAVOIDABLE WITHOUT IMMEDIATE INJUNCTIVE RELIEF.

Although irreparable harm is an analytically distinct prerequisite to preliminary injunctive relief, in trademark infringement actions, irreparable harm "'almost inevitably' follows" where a likelihood of confusion is shown. *Church of Scientology Int'l v. Elmira*

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[4] This section, which establishes Medtech's likelihood of success on the merits, similarly satisfies the serious questions and balance of hardships test alternately employed by this Court. *See Pem-Am., Inc. v. Sunham Home Fashions, LLC*, 83 Fed.Appx. 369, 372 (2d Cir. 2003) (Summary Opinion). The balance of hardships tips decidedly in favor of Medtech, the market leader with years of investment that has a lot at stake. *Tradescape.com v. Shivaram*, 77 F. Supp. 2d 408, 411 (S.D.N.Y. 1999) (considering "which of the two parties would suffer most grievously if the preliminary injunction motion were wrongly decided").

Mission of the Church of Scientology, 794 F.2d 38, 41-2 (2d Cir. 1986). Medtech need only demonstrate a likelihood of confusion "in order to establish both a 'likelihood of success on the merits and irreparable harm.'" *Cartier v. Symbolix, Inc.*, 386 F. Supp. 2d 354, 358 (S.D.N.Y. 2005) (internal citations omitted). Because Medtech has shown a clear likelihood of confusion, Power Products' use of the NIGHTGUARD mark presumptively causes irreparable harm to Medtech. *See id.*

C. POWER PRODUCTS SHOULD BE ENJOINED FROM INFRINGING MEDTECH'S COPYRIGHT.

1. FIRST FACTOR: MEDTECH HAS SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS OF ITS COPYRIGHT INFRINGEMENT CLAIM.

Power Products' liberal use of Medtech's copyrighted material is apparent because the copied warnings are taken verbatim from Medtech's "At-Home Fitting Instructions." "A plaintiff with a valid copyright proves infringement by demonstrating that: (1) the defendant has actually copied the plaintiff's work; *and* (2) the copying is illegal because a substantial similarity exists between the defendant's work and the protectible elements of plaintiff's." *Fisher-Price, Inc. v. Well-Made Toy Mfg Corp.*, 25 F.3d 119, 122--23 (2d Cir. 1994) (internal citations omitted); *ABKCO Music, Inc. v. Stellar Records, Inc.*, 96 F.3d 60, 64 (2d Cir. 1996).

Copying may be proved in several ways, including by a showing that Power Products had access to Medtech's work and that the resulting publications are "similar enough to support an inference that [Power Products] copied [Medtech's] work." *Fisher-Price, Inc.*, 25 F.3d at 123. At this stage of the test, "'probative,' rather than 'substantial' similarity is the correct term in referring to the plaintiff's initial burden of proving actual copying by indirect evidence." *Castle Rock Entertainment, Inc. v. Carol Publishing Gr., Inc.*, 150 F.3d 132, 137 (2d Cir. 1998).

Medtech's "At-Home Fitting Instructions" have been included with its product since October of 2006. Taking the warnings as a whole, the similarities between the two sets are probative of copying by Power Products. *Fisher-Price, Inc.*, 25 F.3d at 123 ("In the context of deciding whether the defendant copied at all (as distinguished from whether it ***illegally*** copied), 'similarity' relates to the entire work, not just the protectable elements." (emphasis in original)).

The language of the warnings was not mandated by the FDA or FDA regulation. The FDA requires that each device submitted to it include proposed labeling which is both appropriate and suitable to the device for which approval is sought. In the case of the Power Products warning labeling, which was copied from Medtech, the labeling was neither dictated nor approved by FDA. Nor could it have been. The Power Products' device was not approved for OTC use and is not a full occlusion dental protector (as compared to the Medtech OTC NIGHTGUARD dental protector, which was FDA approved, with its warnings and labeling).

The question then turns to whether "the copying was improper or unlawful." *See Nihon Keizai Shimbun, Inc. v. Comline Business Data, Inc.*, 166 F.3d 65, 70 (2d Cir. 1999). To determine whether illegal copying has occurred, the "ordinary observer test" is used. This test is expressed simply as "whether an average lay observer would overlook any dissimilarities between the works and would conclude that one was copied from the other." *Nihon Deizai Shimbun,* 166 F.3d at 70; *Castle Rock Entertainment, Inc.*, 150 F.3d at 139. This involves determining "whether 'the copying is quantitatively and qualitatively sufficient' to support a finding of infringement." *Nihon Keizai Shimbun, Inc.* 166 F.3d at 70 (quoting *Ringgold v. Black Entertainment Television, Inc.*, 126 F.3d 70, 75 (2d Cir. 1997)).

Both in the quantitative and qualitative sense, Power Products has copied Medtech's copyrighted material. Clearly, the vast majority of Splintek's online warnings were directly

copied from the "At-Home Fitting Instructions" for Medtech's NIGHTGUARD, in sequence, with only occasional edits to clarify or make it specific to the Power Products product.[5] Hardly any analysis is needed: the similarities are striking and pervasive.

2. SECOND FACTOR: IRREPARABLE HARM TO MEDTECH IS UNAVOIDABLE WITHOUT IMMEDIATE INJUNCTIVE RELIEF.

As in the context of trademark infringement, irreparable injury is presumed after Medtech demonstrates its prima facie case of infringement for Power Products' copying of Medtech's "At-Home Fitting Instructions" and product packaging. *MyWebGrocer, LLC v. Hometown Info, Inc.*, 375 F.3d 190, 193 (2d Cir. 2004) (*citing Merkos L'inyonei Chinuch, Inc. v. Otsar Sifrei Lubavitch, Inc.*, 312 F.3d 94, 96 (2d Cir. 2002)); *NXIVM Corp. v. The Ross Institute*, 364 F.3d 471, 476 (2d Cir. 2004) ("In a copyright case, the irreparable harm requirement can be met by proof of a likelihood of success on the merits."). Thus, this element of the test favors issuance of the injunction and further analysis of this factor is unnecessary.

D. POWER PRODUCTS SHOULD BE ENJOINED FROM ITS CONTINUED UNFAIR COMPETITION IN SELLING ITS PRODUCT ILLEGALLY.

Finally, by marketing and selling an illegal OTC dental protector, Power Products is violating N.Y. Gen. Bus. § 349(a), which provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful." Power Products' illegal OTC sales should be enjoined under Section 349.

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[5] Power Products' product is not a full occlusion mouthpiece, and consists of two bite pads connected by a "thermal sensitive strap." As the strap can break during use, the warnings include a notice to "Discontinue use and replace if breakage occurs." Moreover, Power Products represents that the product can be used during the day, as well as night, and therefore includes a warning that the product should not be used "For more than 12 hours in a 24 hour period." Other than these two minor changes, as shown in Appendix A, the warnings are copied *verbatim* from Medtech.

1. FIRST FACTOR: MEDTECH HAS SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS ON ITS CLAIM THAT POWER PRODUCTS IS VIOLATING NEW YORK'S DECEPTIVE PRACTICES ACT.

Medtech will demonstrate that it has a likelihood of success on the merits of its Section 349 claim, which has three elements:

1. ***Consumer-Oriented Acts***: Power Products' acts and practices are aimed at consumers;

2. ***Deceptive Acts or Practices***: Power Products' acts or practices are objectively likely to mislead a reasonable consumer acting reasonably under the circumstances; and

3. ***Injury***: Medtech, as the complaining party, has been injured by reason of Power Products' offending conduct.

See Boule v. Hutton, 328 F.3d 84, 93-94 (2d Cir. 2003) (quoting *Maurizio v. Goldsmith*, 230 F.3d 518, 521 (2d Cir. 2000)); *In re: Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation*, 175 F. Supp. 2d 593, 630 (S.D.N.Y. 2001).

a. THE CONDUCT OF POWER PRODUCTS IS "CONSUMER-ORIENTED."

Medtech is a proper plaintiff under Section 349(h), which states that "any person who has been injured by reason of any violation of this section may bring an action in his own name to enjoin such unlawful act or practice . . . ." N.Y. CLS Gen. Bus. § 349(h). This language has been interpreted to allow "recovery not only by consumers, but also by competitors if there is '*some harm to the public at large.*'" *Boule*, 328 F.3d at 94 (internal quotations omitted) (emphasis added); *see also Louros v. Cyr*, 175 F. Supp. 2d 497, 517 (S.D.N.Y. 2001) (stating that Section 349 was designed to protect the consumer from injury or prevent harm to the public interest); *Four Winds of Saratoga, Inc. v. Blue Cross and Blue Shield of Central New York, Inc.*, 241 A.D.2d 906, 907, 660 N.Y.S.2d 236, 237 (App. Div. 1997) (stating that Section 349 was designed to prohibit acts and practices that have a broad impact on consumers at large).

Here, the FDA already found that the purpose of the Food, Drug and Cosmetic Act is to *protect the public health, i.e.,* the public at large. In its WARNING LETTER, the FDA found that Power Products' failure to obtain "marketing approval or clearance before [it] began offering [its] product for over the counter use and for use by children 12 – 18 years old" is a "violation of the law." Boyko Decl. ¶ 8 & Ex. 5. The FDA then wrote the following about the purpose of the Federal Food, Drug, and Cosmetic Act:

> The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. **This helps protect the public health** by ensuring that new devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country for which approval is not required. *Id.* (emphasis added)

The FDA has already found that the public at large is protected by the premarket approval regulatory requirement.

b. POWER PRODUCTS' ACTIONS ARE DECEPTIVE.

By using the Medtech NIGHTGUARD brand name, Power Products is deceiving consumers by suggesting that its product is from the same source as the Medtech NIGHTGUARD brand product. By the very act of selling its product OTC, Power Products is misleading consumers into believing that its dental protector is FDA approved for OTC sale, when it is not. Selling the product over-the-counter also violates the recommendations of the FDA's Dental Advisory Panel who, after a full public hearing and public vote, recommended that only full-occlusion mouthpieces to be sold OTC. Such conduct is materially misleading, as consumers are likely to be misled into believing that the product being purchased is safe and effective for OTC use and is otherwise offered for sale in conformity with the law.

Section 349(d) makes an exception for a party that acts in compliance with applicable federal law. N.Y. CLS Gen. Bus. § 349(d) ("In any such action it shall be a complete defense

that the act or practice is, or if in interstate commerce would be, subject to and complies with the rules and regulations of, and the statutes administered by, the federal trade commission or any official department, division, commission or agency of the United States . . . ."). However, Power Products is not doing that. While regulatory compliance can show fairness and candor, thumbing your nose at a federal agency shows unfair competition and deception.

c. MEDTECH HAS BEEN INJURED BY POWER PRODUCTS' ILLEGAL ACTIONS.

Finally, Medtech has been injured by reason of Power Products' illegal actions. First, it is clear that Power Products is illegally commandeering sales of Medtech's dental protectors by marketing an illegal dental protector. As stated by a leading commentary on unfair competition:

> Just as a student who cheats at an examination should be deprived of any advantage thereby achieved, so too the business rival who flouts the law to the detriment of law-abiding competitors is violating the rules of the game, and should be answerable therefore, not only to the governmental authorities but to competitors as well. 2 Altman, *Callmann Unfair Competition Trademarks and Monopolies*, 4th ed., §16:2 (West 8/2003).

Second, if the FDA takes further regulatory action against Power Products, especially considering Power Products' use of Medtech's NIGHTGUARD mark, consumers could be misled into thinking that the Medtech's dental protector is somehow the subject of a regulatory action. This could irreparably damage Medtech's reputation with consumers.

2. SECOND FACTOR: IRREPARABLE HARM FROM POWER PRODUCTS' CONTINUED INFRINGEMENT.

In the Second Circuit, irreparable harm is an injury that cannot be redressed by a monetary award. *Brenntag Int'l Chemicals, Inc. v. Bank of India*, 175 F.3d 245, 249 (2d Cir. 1999); *Standard & Poor's Corp. v. Commodity Exch. Inc.*, 683 F.2d 704, 711 (2d Cir. 1982). This standard is met here, where it will be impossible to calculate with any degree of certainty